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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/925,671	08/09/2001	Bo Arthur Einar Tjellstrom	11133Z	3329

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EXAMINER	
SCHWADRON, RONALD B	
ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 05/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/925,671	TJELLSTROM ET AL.	
	Examiner	Art Unit	
	Ron Schwadron, Ph.D.	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-10 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-10 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. Claims 1-10 are under consideration.

2. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

3. Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hassig (U.S. Pat. No. 4,676,982) in view of Hardie (U.S. Pat. No. 4,477,432), Park et al. and Ibbotson et al. Applicants arguments have been considered and deemed not persuasive.

Hassig teaches and claims a method of treating chronic inflammatory diseases of the bowel, including ulcerative colitis and Crohn's disease, by intravenously administering an effective dose of polyvalent immunoglobulin (see entire document, e.g., Abstract and claims). Inflammatory bowel disease is a form of mucosal inflammation. Hassig teaches that the immunoglobulin preparation is intact IgG obtained from blood serum fractions (i.e., is a pooled human polyclonal immunoglobulin preparation, see column 1 , especially lines 32-48). SANDOGLOBULIN (the IgG preparation referred to in the Examples section) is a preparation containing at least about 25% IgG polyclonal antibodies. Hassig also discloses use of a preparation containing at least 70% IgG which is not antigen specific (see claim 1 and column 5, first incomplete paragraph wherein the IgG is prepared from human serum that would

contain antibodies of all specificities to which the human had been exposed, and therefore the preparation is not antigen specific). Hassig differs from the instant method by not teaching oral administration and the doses and formulations for oral administration. Hardie teaches that immunoglobulin preparations prepared for intravenous administration could also be administered orally without a loss of therapeutic efficacy (see entire document). Hardie teaches that oral administration of Ig, including IgG, has advantages over parenteral (including intravenous) administration because oral administration avoided the pain of an injection, by provided an easy means of administering the composition, and provided an administration route by which larger doses could be administered if needed (see column 2, especially "Summary of the invention"). Hardie teaches formulating the oral immunoglobulin preparation as part of a pharmaceutically acceptable carrier, and teaches encapsulation of the composition, which would provide an enteric coating (see columns 3-4). Hardie teaches that the formulation administered in the examples of the invention for treatment of enteric infection contained 14 mg/dl (1.4 mg/ml-) of IgG and that I-8 ml-kg/day was administered (1.4- 1I2 mg/kg). Thus for an adult of 70 kg, the corresponding dose would be 98-784 mg, which falls within dosage recited in instant claim 7. Park et al. teach the treatment of rheumatoid arthritis using orally administered pooled human IgG at a dosage encompassed by that recited in the claims (see abstract). Thus, the art recognized that orally administered pooled human polyclonal IgG (SANDOGLOBULIN) had been used successfully to treat an autoimmune disease. In addition, Park et al. suggest that the pooled human IgG may neutralize superantigens related to the pathogenic mechanism of rheumatoid arthritis and Ibbotson et al. suggest that superantigens are involved in the pathogenic mechanism in IBD (see page 4, last two paragraphs). It would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have created the claimed invention because Hassig teaches a method of treating chronic inflammatory diseases of the bowel, including ulcerative colitis and Crohn's disease, by intravenously administering an effective dose of polyvalent immunoglobulin pooled human polyclonal whilst Hardie teaches that immunoglobulin preparations prepared for intravenous administration could also be administered orally without a loss of therapeutic efficacy and Park et al. teach the treatment of autoimmune disease with pooled human IgG. The ordinary artisan would

have been motivated to substitute oral administration for intravenous administration because Hardie teaches that oral administration is advantageous compared to parenteral, including intravenous, administration and Park et al. disclose successful treatment of autoimmune disease with orally administered polyclonal pooled human IgG. In addition, Park et al. suggest that the pooled human IgG may neutralize superantigens related to the pathogenic mechanism of rheumatoid arthritis and Ibbotson et al. suggest that superantigens are involved in the pathogenic mechanism in IBD (see page 4, last two paragraphs). Thus one have been motivated to treat IBD with orally administered polyclonal pooled human IgG because of the potential role of superantigens in both IBD and rheumatoid arthritis.

In the amendment filed 3/2/2005, applicant has referred to a plethora of references that are not of record and of which no copy has been submitted. These references have not been considered and applicants comments regarding said references have also not been considered. Regarding applicants comments about a particular WEB page, due to the impermanent and ever changing nature of WEB pages, if applicant desires to have the content of a particular WEB page considered, it needs to be submitted in paper copy. Regarding applicants comments, Hassig teaches and claims a method of treating chronic inflammatory diseases of the bowel, including ulcerative colitis and Crohn's disease, by intravenously administering an effective dose of polyvalent immunoglobulin (see entire document, e.g., Abstract and claims). Inflammatory bowel disease is a form of mucosal inflammation. Thus, the prior art already established that chronic inflammatory diseases of the bowel, including ulcerative colitis and Crohn's disease, could be treated by intravenously administering an effective dose of polyvalent immunoglobulin. The ordinary artisan would have been motivated to substitute oral administration for intravenous administration because Hardie teaches that oral administration is advantageous compared to parenteral, including intravenous, administration and Park et al. disclose successful treatment of autoimmune disease with orally administered polyclonal pooled human IgG. In addition, Park et al. suggest that the pooled human IgG may neutralize superantigens related to the pathogenic mechanism of rheumatoid arthritis and Ibbotson et al. suggest that superantigens are involved in the pathogenic mechanism in IBD (see page 4, last two

paragraphs). Thus one have been motivated to treat IBD with orally administered polyclonal pooled human IgG because of the potential role of superantigens in both IBD and rheumatoid arthritis. The Ibbotson et al. reference provides a variety of evidence that suggests that superantigens are involved in the pathogenic mechanism in IBD (see entire reference) . Regarding applicants comments about Hardie, Park et al. disclose successful treatment of autoimmune disease with orally administered polyclonal pooled human IgG. Regarding applicants comments about Park et al., said reference states: "Rheumatoid arthritis is a systemic disease in which superantigens may be implicated. We decided to administer pooled Ig orally to patients with rheumatoid arthritis with the idea that it might neutralize pathogenic superantigens if present in the gastrointestinal tract.". Regarding applicants comments about Ibbotson et al., the Ibbotson et al. reference provides a variety of evidence that suggests that superantigens are involved in the pathogenic mechanism in IBD (see entire reference) .

4. No claim is allowed.

5. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ron Schwadron, Ph.D. whose telephone number is 571 272-0851. The examiner can normally be reached on Monday to Thursday from 7:30am to 6:00pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached at 571 272 0841. The fax phone number for the organization where this application or proceeding is assigned is

703-872-9306. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

RONALD B. SCHWADRON
PRIMARY EXAMINER
GROUP ~~1800~~ 1600

Ron Schwadron, Ph.D.
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Art Unit 1644